The DYLL REVIEW
We take the worry out of Peer Reviews
25 Highland Park Village #100-177 Dallas TX 75205
Phone: 888-950-4333 Fax: 888-9504-4443

May 28, 2015

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Request Medical Necessity purchase of Exogen Ultrasonic Bone Growth Stimulator

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:

The physician performing this review is Board Certified, American Board of Physical Medicine & Rehabilitation. The physician is certified in pain management. The physician has a private practice of Physical Medicine & Rehabilitation, Electro Diagnostic Medicine & Pain Management in Texas. The physician is a member of the Texas Medical Association and the Houston Physical Medicine and Rehabilitation Society. The physician is licensed in Texas and Michigan and has been in practice for over 25 years.

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

☐ Upheld (Agree)

☒ Overturned (Disagree)

☐ Partially Overturned (Agree in part/Disagree in part)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

Upon independent review the physician finds that the previous adverse determination should be ~ Overturned

PATIENT CLINICAL HISTORY [SUMMARY]:

This patient sustained an injury in a pot hole on xx/xx/xx and a second injury on xx/xx/xx. There are no xray reports but there are comments of a chip avulsion fracture in the physician noted. The ankle MRI arthrogram done 6/2/14 showed disruption of the anterior talofibular ligament, a partial tear of the deep component of the deltoid ligament, and xray dye in along the peronei. There was an

25 Highland Park Village #100-177 Dallas TX 75205
Phone: 888-950-4333 Fax: 888-9504-4443

osteochondral talar dome fracture and a nondisplaced fibula tip fracture (avulsion) that communicated in the joint. She apparently had arthroscopic surgery by to the ankle with ligament repair and removal of the talar fragments on 8/23/14. She remained with symptoms at the tip of the fibula. A second opinion (I could not identify the name as several were on the page) was done 12/17/14. The report commented about the repeat MRI on 12/8/14. The examination demonstrated point tenderness at the fibula,no laxity, and possible symptom magnification. There was no formal MRI report, but the note described a chronic and stable fracture of the distal tip of the fibula with some callus and a stable osteochondral dome defect.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:

There are no xray reports. I have to rely on the description of the fracture from the MRI arthrogram and the medical records. The fracture apparently did not require surgery or excision of the fragment. The ODG, which is the only source allowed in Texas Workers Compensation to be used as a reference for treatment, indicates the device is for long bone fractures. The fibula is a long bone, however, the tip would not be. The knee chapter of the ODG does allow the use if 4 criteria that follow are met:

Nonunions: Low intensity ultrasound treatment may be considered medically necessary in patients with nonunion of bones, excluding the skull and vertebrae, when all of the following criteria are met: (1) At least three months have elapsed since the date of fracture and the initiation of conventional fracture treatments; (2) Serial x-rays have confirmed that no progressive signs of healing have occurred; (3) The fracture gap is one centimeter or less; & (4) fracture is adequately immobilized. **(**Leung, 2004**) (**BlueCross Blue Shield, 2007**)**

The fracture is a year old. There is some callus, but no obvious healing. The fracture gap was not mentioned, but was considered nondisplaced. Xray dye did penetrate it, but I suspect this gap is at most a few millimeters and not a centimeter. The fracture was immobilized in the boot.

As such the device is approved and the denial reversed.

Bone growth stimulators	See Bone growth stimulators, electrical; & Bone growth stimulators, ultrasound.
Bone growth stimulators, electrical	Recommended as an option for non-union of long bone fractures. (Petrisor, 2005) See the Knee Chapter for specific indications.

25 Highland Park Village #100-177 Dallas TX 75205
Phone: 888-950-4333 Fax: 888-9504-4443

Bone growth stimulators, ultrasound	Recommended as an option for non-union of long bone fractures or fresh fractures with significant risk factors. Also, limited studies show that patients who received post-operative low intensity ultrasound following ankle fusion showed a statistically significant faster healing rate on plain radiographs at 9 weeks and CT scan at 12 weeks. A 100% fusion rate was noted. (Coughlin, 2008) (Ishikawa, 2002) (Jones, 2006) (Khan, 2008) (Siska, 2008) Limited evidence has been shown for the use of ultrasound fracture healing in Charcot neuroarthropathy. (Strauss, 1998) See the Knee Chapter for specific indications.

From the Knee Chapter:

25 Highland Park Village #100-177 Dallas TX 75205
Phone: 888-950-4333 Fax: 888-9504-4443

Bone growth stimulators, ultrasound	Recommended as indicated below. Recent studies have shown an accelerating effect of low-intensity pulsed ultrasound (LIPUS) on fracture repair. LIPUS treatment should be started within 6 months of the most recent operation. Because LIPUS has been shown to be effective without causing either serious invasiveness or any undue risk to the patient, it may be considered the treatment of first choice for cases of postoperative delayed union or nonunion. (Jingushi, 2007) (Busse, 2002) (Warden, 2006) Low-intensity pulsed ultrasound has been principally investigated as a technique to accelerate healing of fresh fractures, but more recently as a treatment of fracture nonunions. Ultrasound can be delivered noninvasively with the use of a transducer applied to the skin surface overlying the fracture site. Ultrasound treatment can be self-administered with one daily 20-minute treatment, continuing until the fracture has healed. The mechanism of action at the cellular level is not precisely known, but is thought to be related to a mechanical effect on cell deformation or indirectly, by an electrical effect caused by cell deformation. With respect to healing of fresh fractures, evidence limits use of low-intensity ultrasound to closed fractures. (BlueCross BlueShield, 2005) (Nolte, 2001) (Ricardo, 2006) **The Sonic Accelerated Fracture Healing System (SAFHS) may accelerate healing of fresh fractures, fusions, or delayed unions of the shaft of the tibia that are open or segmental. (When applied over a fracture site, the SAFHS device produces an ultrasonic wave, which delivers mechanical pressure to the bone tissue at the fracture site. Although the mechanism by which the low intensity pulsed ultrasound device accelerates bone healing is uncertain, it is thought to promote bone formation in a manner comparable to bone responses to mechanical stress.) (Aetna, 2004) Evidence for the effect of low intensity pulsed ultrasonography on healing of fractures is moderate to very low in quality and provides conflicting results, when focusing on patient important outcomes, in particular functional recovery, as opposed to radiographic healing as the end point. (Busse, 2009)** **Criteria for the use of Ultrasound fracture healing:** Fresh Fractures: Most fresh fractures heal without complications with the use of standard fracture care, i.e., closed reduction and cast immobilization. However, low intensity ultrasound treatment may be considered medically necessary for the treatment of fresh, closed or Grade I open fractures in skeletally mature adults when at least one of the following significant risk factors for delayed fracture healing or nonunion are present: (1) Diabetes; (2) Osteoporosis; (3) Steroid therapy; (4) Currently smoking; (5) Fractures associated with extensive soft tissue or vascular damage. Other factors that may indicate use of ultrasound bone healing depending on their severity may include: Obesity, nutritional or hormonal deficiency, age, low activity level, anemia, infection, or communited or other especially complicated fractures. Nonunions: Low intensity ultrasound treatment may be considered medically necessary in patients with nonunion of bones, excluding the skull and vertebrae, when all of the following criteria are met: (1) At least three months have elapsed since the date of fracture and the initiation of conventional fracture treatments; (2) Serial x-rays have confirmed that no progressive signs of healing have occurred; (3) The fracture gap is one centimeter or less; & (4) fracture is adequately immobilized. **(Leung, 2004) (BlueCross Blue Shield, 2007)**

The DYLL REVIEW
We take the worry out of Peer Reviews
25 Highland Park Village #100-177 Dallas TX 75205
Phone: 888-950-4333 Fax: 888-9504-4443

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

- ☐ ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE
- ☐ AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES
- ☐ DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES
- ☐ EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN
- ☐ INTERQUAL CRITERIA
- ☐ MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS
- ☐ MERCY CENTER CONSENSUS CONFERENCE GUIDELINES
- ☐ MILLIMAN CARE GUIDELINES
- ☒ ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES
- ☐ PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR
- ☐ TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS
- ☐ TEXAS TACADA GUIDELINES
- ☐ TMF SCREENING CRITERIA MANUAL
- ☐ PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)
- ☐ OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)